#19
OL

Our Docket No. 990356.CON

3-17-04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App	:	Nuss	
S.N.	:	09/760,136	Art Unit 3736
Filed	:	01/12/2001	Examiner Foreman
For	:	Titanium Molybdenum Alloy Guidewire	

REQUEST FOR RECONSIDERATION

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This request for reconsideration is submitted in response to the Office Action dated 2/05/2004.

Respectfully submitted,

NIKOLAI & MERSEREAU, P.A.

March 3, 2004

Steven E. Kahm

Steven E. Kahm
Attorney for Applicant
Registration No. 30860
900 Second Avenue South
Suite 820
Minneapolis, MN 55402
Phone: 612-339-7461

REQUEST FOR RECONSIDERATION

In the last office action the examiner took the following position to establish obviousness of the applicant's claims 12-27.

The examiner stated:

"Claims 12 — 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent Application Publication No. 2003/0009215 to Mayer.

In regards to claims 12-27, Cornish et al. discloses a guidewire comprising a titanium alloy core wire having a proximal end and a distal end, the distal end having a smaller diameter than the proximal end; a taper of the diameter between the distal end and the proximal end with the distal end being smaller (Col. 3, line 66 - Col. 4, line 14); a coil (20) attached to the distal end; a distal tip (58) on the distal end; a polymer coating and a hydrophilic coating (Col. 3, lines 50-60). Cornish et al. discloses the wire being formed of any suitable material (Col. 3, lines 42 - 47). However, Cornish et al. fails to disclose the titanium alloy being a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight. Mayer discloses a medical device for inserting into body passageways during medical procedures including a titanium molybdenum alloy wire having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight [0078]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the titanium alloy as disclosed by Cornish et al. to include a titanium molybdenum alloy as taught by Mayer in order to avoid undue irritation to patients having a sensitivity to nickel [0079]. Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960)."

According to the Manual Of Patent Office Procedure the examiner has not made out a *Prima Facie* case of obviousness.

MPEP 2143 Basic Requirements of a *Prima Facie* Case of Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest **all** the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

2141.01(a) Analogous and Nonanalogous Art

TO RELY ON A REFERENCE UNDER 35 U.S.C. 103, IT MUST BE ANALOGOUS PRIOR ART

The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); and *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

The examiner has erred since there is no suggestion or motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. This is particularly true when the examiner must show the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned."

The examiner states that the motivation to combine the teachings of Mayer with Cornish is to undue irritation in to patients having sensitivity to nickel as taught by Mayer.

Firstly this is a false statement since there is no problem with sensitivity to nickel in guidewires. Guirewires typically do not remain in the body for more than a matter of a few minutes. Stents, on the other hand, are meant for permanent installation. There is no reason for a guidewire maker to look to the art relative to stents to solve the problem of sensitivity to nickel in the body. Guidewires are only in the body for a short time and withdrawn. No allergic reactions occur. Further, a person skilled in the art of guidewires knows that guidewires are coated such that the alloy of the guidewire itself does not come in contact with the patient and therefore nickel content in the guirewire is definitely not an issue. The examiner has made up a nonexistent issue for linking the Mayer stent to the Cornish guidewire.

Secondly the reason to look to another art for a solution to a problem has to be for solving a problem the applicant has identified in his application. Here, the applicant states the problem as being the flexibility, softness, pushability, properties of kinking, springiness, torque transmission, bendability, memory, stress and strain of the materials used to make a guidewire. Nothing in either reference shows what the properties of a titanium, molybdenum, zinc and tin alloy guidewire would be or whether those properties would be useful in a guidewire.

The Mayer reference pertains to a stent. A stent generally has a small profile as it is being inserted into the body and expands to a larger cross section when placed in the desired place within the body. These properties are not the same as those desired for a guidewire which has to have steerability, flexibility, and torqueability without kinking. These are the problems the applicant stated he was trying to overcome in the application. These are the problems which the references must address if they are to be applied in an obviouness rejection. Neither reference, by itself or combined, talks about these issues or that the titanium, molybdenum, zinc and tin alloy claimed would make a good guidewire. Therefore the examiner has not met his *Prima Facie* case of obviousness and the claims should be allowed over his objection.

The second test for *Prima Facie* case of obviousness is that there must be a reasonable expectation of success. There are no teachings in either the Mayer stent reference or the Cornish guidewire reference indicating that the claimed alloy of titanium, molybdenum, zinc and tin alloy claimed would result in an improved guidewire. Therefore the examiner has again failed to make a *Prima Facie* Case of Obviousness.

The third test for *Prima Facie* Case of Obviousness is that, the prior art reference (or references when combined) must teach or suggest **all** the claim limitations. As shown above, the Cornish guidewire reference teaches guidewires made from stainless steel or nickel titanium alloy (NITINOL) or some material with similar properties. The examiner has combined Cornish with Mayer which shows a stent made from a titanium, molybdenum, zinc and tin alloy. The references do not teach or suggest the combination. There is no way a person skilled in the art would know from combining the teachings or suggestions of the Cornish and Mayer references that a titanium, molybdenum, zinc and tin alloy could be made into a guidewire that would have the desired properties of a guidewire for use in guiding intravascular catheters.

Since the examiner has failed to make a *Prima Facie* Case of Obviousness the claims should be allowed.

The examiner has also appears to have misapplied *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960) which holds, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. There is no showing in either reference that a titanium, molybdenum, zinc and tin alloy would be suitable for a guidewire. It was not know that a titanium, molybdenum, zinc and tin alloy was suitable for a guidewire or could be fashioned into a guidewire before the applicant did so. Nor is there a design consideration involved with a simple substitution of materials as in *In re Leshin*.

The applicant believes the examiner erred in rejecting the claims as being obvious and that the claims should be allowed since the cited references do not make out a *Prima Facie* case of obviousness.

It is respectfully requested that this Request for Reconsideration be entered to thereby better frame the issues for appeal should the examiner adhere to his position.